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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,671	12/20/2005	Anders Vikso Nielsen	10473.204-US	3643

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
04/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,671	NIELSEN ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-59 and 61-65* is/are pending in the application.

4a) Of the above claim(s) *61-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/7/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Alignment 1*.

DETAILED ACTION

A response and amendment were received and entered on January 6, 2010. Claims 1-46 and 60 are cancelled. Claims 47-59 and 61-65 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, as set forth in the restriction requirement mailed on February 12, 2009, in the reply filed on March 12, 2009 was acknowledged and made final in the Office action mailed on August 6, 2009. Applicant's traversal with respect to the lack of unity has been noted; applicant is advised that if the technical feature recited in the claims is found to possess an inventive step, the restriction requirement will be withdrawn. Presently, the requirement for restriction has been maintained because the technical feature that is common to the groups lacks an inventive step for the reasons set forth in the previous office action and below.

2. Claims 61-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

3. Claims 47-60 are examined on the merits in this office action.

Claim Rejections - 35 USC § 112

4. Rejections under 35 USC 112 are withdrawn due to amendment.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 47-56 stand rejected under 35 U.S.C. 103(a) as obvious over Shi et al. (US 6,054,302) in view of Walon (US 4,235,965), as evidenced by the attached sequence alignment (Alignment 1, which can be found as Result 1 under the

Alignments section in the search results filed on August 6, 2009 and again on January 28, 2010). Claim 47 recites a process for producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature of said granular starch to the action of a first enzyme and a second enzyme, wherein (a) the first enzyme (i) is a member of the glycoside hydrolase family 13; (ii) has alpha-1,4-glucosidic hydrolysis activity, and; (iii) comprises a functional carbohydrate-binding module (CBM) belonging to CBM family 20, wherein the CBM comprises an amino acid sequence having at least 90% homology to SEQ ID NO:2. Claim 48 recites that the CBM of claim 47 comprises an amino acid sequence having at least 95% homology to the amino acid sequence of SEQ ID NO:2. Claim 49 recites that the starch slurry has 20-55% dry solids granular starch. Claim 50 recites that at least 85% of the dry solids of the granular starch are converted into a soluble starch hydrolysate. Claim 51 recites that the granular starch is further subjected to the action of isoamylase and pullulanase. Claim 52 recites that the temperature is at least 58 degrees C. Claim 53 recites that the pH is 3.0 to 7.0. Claim 54 recites that the soluble starch hydrolysate has a DX of at least 94.5%. Claims 55 and 56 recite that the granular starch is derived from a variety of sources. Claim 60 recites that the first enzyme does not comprise a catalytic module.

9. Shi discloses a method of producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature to the action of two or more enzymes (abstract, col. 4, lines 15-31, col. 9, lines 46-49). The enzymes used in the method of Shi are alpha amylase,

beta amylase or glucoamylase, such as a fungal or bacterial enzymes (col. 6, lines 15-29, col. 9, lines 46-49). The reference teaches that 30-50% dry solids may be used in the slurry (col. 3, liens 16-21), that conversion rates of 85% could be achieved (col. 1, line 62-col. 2, line 2), and that the slurry could also be subjected to isoamylase or pullulanase (col. 6, lines 15-29). The process of Shi uses temperatures greater than 58 degrees C and a pH from 3.0 to 7.0 (col. 10, lines 20-36), and uses the claimed starch sources (col. 5, lines 35-45). The reference does not specifically disclose the use of an enzyme comprising the CBM and nucleotide sequence recited in the claims.

10. Walon teaches a method for producing a soluble starch hydrolysate by subjecting a granular starch slurry at a temperature below its initial gelatinization temperature to a bacterial alpha amylase (abstract). The reference teaches that any suitable bacterial amylase may be used in the method, particularly those from *Bacillus* spp. (col. 2, lines 52-68).

11. At the time of the invention, methods for producing soluble starch hydrolysates comprising nearly all of the claimed elements were known, as taught by Shi and Walon. It was further known that multiple enzymes could be used in such methods, as taught by Shi, and that alpha amylases from *Bacillus* spp. were suitable in such methods, as taught by Walon. One of ordinary skill in the art would have been motivated to use an enzyme comprising the CBM recited in the claims because an enzyme comprising the CBM recited in the claims is an alpha amylase from a *Bacillus* spp. (see attached Alignment 1). Since Walon teaches that any bacterial alpha-amylase could have been used in the method, particularly one from *Bacillus* spp., and an alpha amylase

comprising the claimed sequence from a *Bacillus* spp. existed at the time of the invention, one of ordinary skill in the art would have recognized that an enzyme meeting the limitations recited in the claims could have been selected at the time of the invention from the finite number of possibilities for use in the claimed method. Furthermore, one of ordinary skill in the art practicing the invention of the prior art could arrive at the claimed results, such as DX values recited in the claims, in the course of routine experimentation, since DE values of 100% were known in the art, as taught by Shi (col. 4, lines 56-65). One of ordinary skill in the art would have had a reasonable expectation of success in using the enzyme of the claims because it was known in the art that alpha amylases from *Bacillus* spp. could have been used in methods for starch hydrolysis at the time of the invention. It would therefore have been obvious at the time of the invention to combine the teachings discussed above to arrive at the claimed invention.

12. Claims 47-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi et al. (US 6,054,302) in view of Walon (US 4,235,965), as evidenced by the attached sequence alignment (Alignment 1, which can be found as Result 1 under the Alignments section in the search results filed on August 6, 2009 and again on January 28, 2010), as applied to claims 47-56 and 60 above, and further in view of Leach (3,922,196). Claims 47-56 and 60 are discussed above. Claims 57-59 recite that the process of claim 47 is conducted in an system with ultrafiltration or microfiltration membranes and where the retentate is held under recirculation in the presence of

enzymes, raw starch and water, and where the permeate is the soluble starch hydrolysate.

13. Shi discloses a method of producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature to the action of two or more enzymes (abstract, col. 4, lines 15-31, col. 9, lines 46-49). The enzymes used in the method of Shi are alpha amylase, beta amylase or glucoamylase, such as a fungal or bacterial enzymes (col. 6, lines 15-29, col. 9, lines 46-49). The reference teaches that 30-50% dry solids may be used in the slurry (col. 3, liens 16-21), that conversion rates of 85% could be achieved (col. 1, line 62-col. 2, line 2), and that the slurry could also be subjected to isoamylase or pullulanase (col. 6, lines 15-29). The process of Shi uses temperatures greater than 58 degrees C and a pH from 3.0 to 7.0 (col. 10, lines 20-36), and uses the claimed starch sources (col. 5, lines 35-45). The reference does not specifically disclose the use of an enzyme comprising the CBM and nucleotide sequence recited in the claims.

14. Walon teaches a method for producing a soluble starch hydrolysate by subjecting a granular starch slurry at a temperature below its initial gelatinization temperature to a bacterial alpha amylase (abstract). The reference teaches that any suitable bacterial amylase may be used in the method, particularly those from *Bacillus* spp. (col. 2, lines 52-68).

15. At the time of the invention, it would have been obvious to combine the teachings discussed above to arrive at the claimed invention, as discussed in detail in the above

rejections. None of the references, however, teach that the reaction is conducted in the presence of the membranes recited in the claims.

16. Leach teaches a method for the enzymatic hydrolysis of granular starch wherein the process may occur in the presence of a membrane, such as an ultrafiltration membrane, wherein the retentate is held in the presence of membranes and the permeate is the soluble starch hydrolysate (abstract; col. 8, lines 32-39).

17. Nearly all of the elements of the claimed process were known in the art at the time of the invention, as taught by Shi and Walon. It was further known that methods for the production of soluble starch hydrolysates could be conducted in the presence of filtration systems, as taught by Leach. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed invention because Leach teaches that the method is advantageous because it allows separation of the unreacted components from the reacted product. One of ordinary skill in the art would have had a reasonable expectation of success, and the selection of a filtration membrane for the use in such a method would have been considered a routine matter of experimentation, because the use of filtration methods with starch processes was well known in the art at the time of the invention, as taught by Leach. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

18. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed January 6, 2010 have been fully considered but they are not persuasive. Applicant argues that the cited prior art does not render the claimed invention obvious because the alignment referred to in the rejections above is not prior art. However, the alignment is cited only to provide evidence of inherent characteristics of prior art *Bacillus* enzymes, and need not itself be a prior art reference. The alignment provides evidence that enzymes containing the characteristics recited in the claims, specifically the recited homology to SEQ ID NO:2, existed in the art at the time of the invention in alpha-amylases of *Bacillus* spp. At the time of the invention, the use of such enzymes in processes such as those recited in the claims was known in the art. Since the art suggests that a variety of *Bacillus* enzymes are suitable for use in these methods, one of ordinary skill in the art would have recognized that a suitable enzyme could have been selected from a number of enzymes, and thus a *Bacillus* enzyme possessing the claimed characteristics could have been chose from a finite number of predictable solutions, as discussed in the above rejections. Applicant is reminded that discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new; thus the claiming of a new use, functions or unknown property that is inherently present in the prior art does not necessarily make the claim patentable (see MPEP 2112). Since enzymes possessing the claimed characteristics were known at the time of the art, as were processes of using similar enzymes in prior art processes, the

discovery of a new property (i.e., the sequence of the enzyme), does not render the prior art enzyme patentable. Although applicant further argues that Alignment 1 (which can be found as Result 1 under the Alignments section in the search results filed on August 6, 2009 and again on January 28, 2010) discloses only a carbohydrate binding module (CBM) and not an alpha-amylase, it is noted that the alignment not only discloses that the sequence is a CBM and that alpha-amylases may possess this CBM (see, for instance, the description of claim 2 is the supporting information included with Alignment 1). Therefore, the alignment does provide evidence that prior art alpha-amylases could have been selected that possessed the characteristics recited in the claims.

19. Thus, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651